DETAILED ACTION

Response to Restriction

1. Applicant's election of Group I encompassing claims 1-16 in the reply filed on 11/23/2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Therefore, this restriction requirement is deemed proper and is made final.

2. Claims 6, 8, 12 and 14-18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species and/or invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 11/23/2007 due to an incomplete response.

3. Claims 1-5, 7, 9-11 and 13 are therefore presented for examination on the merits. The following rejections are made.

Applicants Claims

4. The instant claims are drawn to a conjugate particle comprising a fine porous particle (i.e. silica) on which a functional substance (i.e. antimicrobial) which is adhered to the surface thereof through interactions with a water-soluble polymer. The silica particle has an average particle size of 10 nm to 10 mm, and has pores of a diameter of 10 um to 1 nm. The water-soluble polymer is polyethylene glycol wherein the polymer also has a functional group capable of forming a covalent bond to the silica. Specifically, the polymer molecule has the formula

R^1-L_1-$(CH_2CH_2O)_n$-L_2-X (I)

wherein R^1 may be hydrogen, L_1 and L_2 denotes a valence bond or a linker, X denotes a functional group such as a carboxyl and n is an integer from 2 to 20,000. The conjugate is present in a composition and slowly releases a physiologically active substance or an antimicrobial.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. **Claim 1-4, 7, 9-11 and 13 is rejected 35 U.S.C. 102(b) as being anticipated by Hammen et al. (US 5240602).**

7. Hammen ('602) is drawn to drawn to a chromatographic material capable of specific adsorption for use in affinity chromatography (see abstract). The composition disclosed by '602 has the generic formula

S-B-X-Y' (see claim 1) (II)

S is a substantially non-compressible solid support comprising silica, B is a binding group containing silicon covalently linked to a silanol group of S through a siloxane bond, X is a substantially nonionic hydrophilic spacer covalently linked to B comprising polyethylene glycol having between 4 and 300 ethylene glycol units, and Y' is an activated coupling group covalently

linked to X (see claim 1). An exemplified silica containing compound is that having the following structure

Silica-PEG-[COOH] (see Table 2) (III)

Structure III is capable of forming a direct linkage with a antimicrobial such as quinacrine (see Table 1) through a coupling reaction involving the carboxyl terminal of the funtionalized PEG chain and the amine moiety of the quinacrine by reacting them together with the coupling agent, carbodiimide (see Table 2). The properties of the structures present in '602 meets the structural requirements present in the instant claims.

8. The recitation that the composition is capable of slowly releasing physiologically active substances or antimicrobial agents is inherent in the invention of '602. Since the structural details present in the reference is identical to that instantly claimed, the chemical structure must inherently have the property of slowly releasing the antimicrobial agent. The elucidation of a new mode of action or a new property for a compound does not impart patentable moment to old and known subject matter. In the instant invention, the claims are directed to such subject matter which has already been established in the prior art. Therefore, the disclosed functions within the instant application do not render the composition patentably distinct over the prior art.

9. Thus, the instant limitations are met entirely by the '207 and the claims are anticipated.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. **Claims 1-5, 7, 9-11 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hammen (US 5240602) in view of Hou et al. (US 4724207).**

13. Hammen ('602) is drawn to drawn to a chromatographic material capable of specific adsorption for use in affinity chromatography (see abstract). The composition taught by '602 has the generic formula

S-B-X-Y' (see claim 1) (II)

S is a substantially non-compressible solid support comprising silica, B is a binding group containing silicon covalently linked to a silanol group of S through a siloxane bond, X is a substantially nonionic hydrophilic spacer covalently linked to B comprising polyethylene glycol having between 4 and 300 ethylene glycol units, and Y' is an activated coupling group covalently linked to X (see claim 1). An exemplified silica containing compound is that having the following structure

Silica-PEG-[COOH] (see Table 2) (III)

Structure III is capable of forming a direct linkage with a antimicrobial such as quinacrine (see Table 1) through a coupling reaction involving the carboxyl terminal of the funtionalized PEG chain and the amine moiety of the quinacrine by reacting with carbodiimide (see Table 2).

14. The recitation that the composition is capable of slowly releasing physiologically active substances or antimicrobial agents is inherent in the invention of '602. Since the structural details present in the reference is identical to that instantly claimed, the chemical structure must inherently have the property of slowly releasing the antimicrobial agent. The elucidation of a new mode of action or a new property for a compound does not impart patentable moment to old and known subject matter. In the instant invention, the claims are directed to such subject matter which has already been established in the prior art. Therefore, the disclosed functions within the instant application do not render the composition patentably distinct over the prior art.

15. '602 fails to teach the silica particle as having an average particle size of 10 nm to 10 mm and has pores of a diameter of 10um to 1 nm.

16. The teaching of Hou et al. ('207) cures this deficiency. '207 is drawn to modified siliceous chromatographic supports which are useful as selective adsorbents (see column 7, lines 40-41). Specifically, the invention of '207 comprises silica material which comprises silica covalently bonded to a synthetic polymer, wherein the synthetic polymer is made from a polymerizable compound which has a chemical group capable of direct or indirect covalent coupling to silica in combination with to a biologically active molecule (see column 7, lines 5-15). The term "biologically active molecule" is defined by '207 as to encompass antibiotics which is within the scope of antimicrobial (see column 13, lines 46-49). The silica material used

in '207 has a specific surface area of 5 to 1500 m^2/g, a pore diameter of 20 to 2000 A and a particle diameter of 1 um to 1 mm (see column 7, lines 50-55).

17. Thus, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to combine the teachings of '602 with '207 because in doing so one would result with a silica particle containing a water-soluble functionalized polyethylene glycol coating capable of selectively adsorbing biologically active molecules. The significance of '602 is that it teaches a silica particle that has linked to its surface a biologically active agent such as quinacrine (see structures II and III above) which can be effectively used in affinity chromatography for recognition of DNA and RNA sequences. The major shortcoming of '602 is that it fails to specifically teach the dimensions of the silica particle being used although the reference of '602 does state that the an increased adsorption rate corresponded to pore size (see column 8, lines 5-10). The importance of '207 is that it teaches the specific dimensions which are required by the instant claims. As the teachings of the references are within the same general field of endeavor (i.e. affinity chromatography column support), it would have been obvious to one ordinarily skilled in the art to combine them and arrive at a composition with the limitations of the instantly claimed invention. Therefore, it would have been obvious to one of ordinary skill in the art to combine the teaching of '602 with '207 with a reasonable expectation of success.

Conclusion

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kyle A. Purdy whose telephone number is 571-270-3504. The examiner can normally be reached from 9AM to 5PM.

19. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisors, Ardin Marschel and Cecilia Tsang, can be reached on 571-272-0718 or 571-272-0562, respectively. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

20. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Kyle A. Purdy/
Examiner, Art Unit 4173

/Cecilia Tsang/
Supervisory Patent Examiner, Art Unit 4173